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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,721	02/07/2005	Kunihiko Tominaga	50049-046	1065
20277 7590 06/20/2007 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			EXAMINER LEITH, PATRICIA A	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 06/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,721	Applicant(s) TOMINAGA, KUNIHICO	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6 are pending in the application and were examined on their merits.

Drawings

The previous objection to the drawing is overcome due to Applicant's persuasive arguments. However, new corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because there are Japanese characters in the figure. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 remain rejected under this statute for the following reasons. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The Examiner cannot delineate the metes and bounds of the scope of what is sought to be patented, and therefore the ordinary artisan would not be able to ascertain exactly what Applicant intends to claim. Further, the claims include sentences with periods; this constitutes indefiniteness as well, as it cannot be determined if the matter present after the periods is actually part of the claims. Because the Examiner cannot determine what is being claimed, these claims were not examined on their merits. The Examiner cannot what the ingredient of claims 4-6 in order to actually search it on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 remain rejected and claims 4-6 are newly under 35 U.S.C. 102(b) as being anticipated by Katayama (JP408275751A – English abstract) in light of Katayama (JP 06293649A – Application publication – English Abstract).

Applicant's arguments were fully considered, but not found persuasive.

Applicant principally argues that Katayama (1 and 2) do not disclose the fermented soybean milk for use as an intervaginal washing agent, however, discloses the use of the extracted, fermented soybean milk as a wound healing drug (pp. 5-7). The Examiner has considered the intended use for patentable weight. It is deemed that the intended use in the Instant claims does not materially change the composition in that the intended use does not materially change the composition. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). When the claim recites using an old composition or structure and the use is directed to a result or property of that composition or structure, then the claim is anticipated (MPEP 2100 pp. 2113). It is further deemed that the composition resulting from the extraction of fermented soybean milk would not be precluded for topical administration.

Applicant further claims that Katayama did not specifically teach 'fermented soybean milk' (p. 6, Arguments). The Examiner respectfully disagrees in that the reference

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clearly teaches that the extract is obtained after fermentation of the soybean milk via inoculation with several types of bacteria (see English Abstract). Further, it is deemed that because Katayama disclosed that the soybeans were swollen with water, blended and heated, that the resulting composition prior to fermentation was 'soybean milk'.

With regard to claims 4-6 which were amended to overcome the previous rejections under 35 USC 112 second paragraph, it is deemed that these claims do not materially change the composition of claims 1-3 in that claims 4-6 do not describe any inherent characteristics of the composition, but merely state how the extract performs on a chromatography column. Absent evidence which would indicate that the prior art alcoholic extract of fermented soybean milk would not display the characteristics of claims 4-6, these claims are deemed anticipated.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith

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Primary Examiner
Art Unit 1655

June 4, 2007

A handwritten signature in black ink, appearing to read "Patricia J. [unclear]". The signature is written in a cursive style with a large initial "P" and a long, sweeping underline.